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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,513	02/25/2002	Peter Daniel	101195-67	5937

27387

7590

07/17/2003

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/979,513

**Applicant(s)**

DANIEL ET AL.

**Examiner**

Jeanine A Goldberg

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to methods of screening the effect of different chemotherapeutic agents for expression profiles or mutations of **nucleic acids** and comparing the changes associated with the agents.

Group II, claim(s) 1-10, drawn to methods of screening the effect of different chemotherapeutic agents for expression profiles or mutations of **proteins** and comparing the changes associated with the agents.

### **Restriction Requirement Applicable to All Groups:**

2. The claims recite numerous different genes including Bax, p53, p16, caspases, Rb etc. Each gene is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. A restriction is applied to each Group. The effects and expression patterns of each of the genes do not share the same special technical feature. Applicant is required to select one of the genes for examination.

Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record

showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature is a contribution over the prior art. The inventions listed in Group I do not relate to a single general inventive concept because the lack of the same or corresponding special technical feature. The technical feature of Group I is "a method for detecting the effect of different chemotherapeutic agents by analyzing expression profiles of various genes including Bax and determining the changes associated with chemotherapeutic agents" which is shown by Tai et al. (J. of Clinical Oncology, Vol. 16, pages 2583-2590, August 1998- abstract only). Tai teaches the expression of Bax sensitizes ovarian cancer cell lines to paclitaxel (chemotherapeutic agent). Bax protein expression, mRNA transcript levels and mutational analysis was analyzed. Tai specifically teaches that all patents whose tumors expressed high levels of Bax achieve a complete response to first-line chemotherapy that contained paclitaxel compared to the low expressors. Therefore, Tai

indicates that the instant claims lack novelty or inventive step and do not make it a contribution over the prior art.

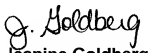
Moreover, Lowe et al. (Science, Vol. 266, pages 807-810, November 1994) teaches that inactivation of p53 can produce treatment-resistant tumors and p53 status may be an important determinant of tumor response to therapy.

The inventions of Group I and II are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I is for detecting nucleic acids. Alternatively, the method of Group II is for proteins. Therefore the methods are distinct over one another.

Moreover, methods of detecting a particular gene is patentably distinct from a method of detecting another gene. For example, methods of detecting Bax are patentably distinct from methods of detecting p53. The search required for each of the distinct methods is not coextensive. Therefore, a separate search and consideration would be required to search each of the methods of detecting Bax and p53 in the same application.

4. A telephone call was made to Ted Gottlieb on July 13, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant requested the restriction in writing.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.
- If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.
- Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
**Jeanine Goldberg**  
**Patent Examiner**  
July 14, 2003